342, 344, 371) and under authority delegated to the Commissioner (21 CFR 2.120), § 90.20 of Subpart B is amended by revising paragraph (j) to read as follows:

§ 90.20 Thermal processing of low-acid foods packaged in hermetically sealed containers.

* * * * *

(j) Compliance with State regulations: (1) Wherever the Commissioner finds that any State regulates the commercial thermal processing of low-acid foods in accordance with effective regulations specifying at least the requirements of Part 128b of this chapter, he shall issue a notice stating that compliance with such State regulations shall constitute compliance with Part 128b. However, the provisions of this section shall remain applicable to the commercial processing of low-acid foods in any such State, except that, either the State through its regulatory agency or each processor of low-acid foods in such State shall file with the Bureau of Foods the registration information and the processing information prescribed in paragraph (c) of this section.

(2) The Commissioner finds that the regulations adopted by the State of California under the laws relating to cannery inspections governing thermal processing of low-acid foods packaged in hermetically sealed containers satisfy the requirements of Part 128b of this chapter.

Accordingly, processors, who under the laws relating to cannery inspections are licensed by the State of California and who comply with such state regulations, shall be deemed to comply with the requirements of Part 128b of this chapter.

* * * * *

As this amendment merely clarifies an existing regulation, notice and public procedure and a delayed effective date are not necessary prerequisites to the promulgation of this order.

Effective date. This order shall become effective on March 13, 1975.

(Secs. 402, 404, 701; 52 Stat. 1046-1047 as amended, 1048, 1055-1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 342, 344, 371))

Dated: March 6, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-6561 Filed 3-12-75;8:45 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

General Labeling Conditions

The Commissioner of Food and Drugs issued a proposal to amend § 330.1 (21 CFR 330.1), published in the FEDERAL REGISTER of June 4, 1974 (39 FR 19880), by revising the general warning statement required in § 330.1(g) to state: "Keep this and all drugs out of reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately," and by revoking § 330.1(i), which contained the following drug interaction warning:

Warning: Do not take this product concurrently with a prescription drug except on the advice of a physician.

Interested persons were invited to submit written comments regarding the proposal on or before August 5, 1974.

A total of seventeen comments were received: one from a national pharmacy association, one from a state consumer assembly, two from pharmaceutical companies, and thirteen from private consumers. The significant comments submitted and the Commissioner's conclusion are as follows:

1. Although concurring in the proposed new form of the general warning statement, one comment requested that an additional statement be required on the labeling of all OTC drugs in the interest of maximizing the potential for safe and effective use of such drugs. The recommended statement was as follows: "If you do not understand any of the following warnings or directions seek professional assistance." The comment said the statement would result in OTC drug labeling that would assure the safe and effective use of such products.

The Commissioner concludes that such a statement should not be required to appear on the labeling of all OTC drugs. The Commissioner concludes, on the basis of the judgment and experience of the agency, that most individuals will seek such professional assistance, if needed, even in the absence of such a statement in the labeling. No evidence was submitted with the comment to support the need for such a statement. It is also recognized that if labeling contains too many required statements, especially general statements of common sense, the impact of all warning statements on the label will be reduced. In addition there is a space limitation on the number of statements that can appear on the labeling.

2. There was comment that the required statement was unnecessarily long especially since many OTC drugs are sold in small containers with limited space available for required statements. In place of the proposed statement, the following statement was suggested: "Keep out of the reach of children. If accidentally misused, seek professional help or contact Poison Control Center immediately." Another comment pointed out that the proposed wording was appropriate for systemically administered drug products, but not for topically applied medication such as lotion, creams, and ointments. For such products it was suggested that the phrase "In case of accidental ingestion" be substituted for "In case of accidental overdose." The comment went on to state that the inclusion of such a statement would be more feasible than requiring individual manufacturers of these products to petition for an exemption from or variation in the general warning.

The Commissioner concludes that the wording of the general warning in § 330.1(g) is proper and that all drugs must contain the statement "Keep this and all drugs out of reach of children." The Commissioner believes that the proposed phrase "In case of accidental ingestion" for topical products is appropriate and the regulation is so modified. The Commissioner further concludes that it is also proper, where appropriate, to grant an exemption from all or part of the following warnings: "In case of accidental overdose, seek professional assistance or contact a poison control center immediately" and "In case of accidental ingestion, seek professional assistance or contact a poison control center immediately." Such exemptions may be granted by category of drug, e.g., medicated soap and anti-caries toothpaste, or by individual products. Since this requirement will apply only when a monograph becomes effective, such exemptions can readily be handled as each monograph proceeds through the OTC drug review procedure. Exemptions will be placed in a permanent file in the Office of the Hearing Clerk, Food and Drug Administration.

3. There was comment that the phrase "contact a Poison Control Center" should be omitted from the required statement. One comment indicated that the reason it should not be included is that, according to their local sources, the poison control center responds better to doctors than to consumers seeking assistance. The other comment stated that poison control centers are not listed in most phone books. Several comments from individual consumers, as well as from a state consumer assembly representing over one million consumers, indicated their strong support for the proposed reference to the poison control center. Many of these comments stated that it was in the consumers' interest to be alerted to the fact that there is more than one source of assistance available in case of an emergency.

The Commissioner concludes that the phrase regarding poison control centers in the statement serves a valuable purpose and should remain in the required statement. As previously stated in the preamble of the proposal, the Commissioner concluded that it would be in the best interest of the consumer to have knowledge that there is more than one source of professional assistance available. The Commissioner recognizes that in a few isolated localities, poison control centers may prefer to respond to health professionals. However, such centers are the exception. Nationwide, approximately 70 percent of the calls responded to were made by non-health professionals.

Although some poison control centers may not be listed in the local telephone directory in some areas of the country, the Commissioner believes that such instances are the exception. This provides

no reason for deleting a general reference to the poison control center in the warning as an alternative source of assistance.

4. One comment was received from an individual consumer asking if lay individuals will know what constitutes an "accidental overdose."

The Commissioner believes that most individuals using OTC drugs will be able to determine what constitutes an "accidental overdose." The labeling contains adequate directions for use including the recommended dosage per time interval (e.g., every 4 hours) or time period (e.g., 4 times a day). Where applicable, the maximum daily dosage for the product will also be included. The consumer will therefore be able to determine what constitutes an accidental overdose. The Commissioner concludes that there is no need for changing the wording.

5. Several comments objected to the proposed revocation of § 330.1(i). These comments indicated that, since people using OTC drugs are not physicians, they would not be aware of possible drug interactions and therefore the general warning statement should be retained.

The Commissioner concludes that the basis for the objections is a misunderstanding of the intent of the proposal. The revocation of § 330.1(i) was proposed because the Commissioner was of the opinion that the proper way to handle possible drug interactions is to require that the labeling of OTC drugs include a separate section headed "Drug Interaction Precautions." Using this approach, in lieu of a general statement appearing in the labeling of all OTC drugs, a statement will be required in the labeling that is specific for the particular OTC drug. As one of the several comments in favor of this proposal indicated, a general warning often goes unheeded but a specific statement for a specific drug or class of drugs will be much more effective.

6. With respect to drug interactions, one comment stated that, although the preamble to the final antacid monograph published in the FEDERAL REGISTER of June 4, 1974 (39 FR 19862) set forth specific drug interaction statements for antacids containing charcoal and kaolin, such statements did not appear in the antacid monograph.

Antacids containing charcoal or kaolin as ingredients have been determined by the Commissioner to be products for which available data are insufficient to permit final classification. If such active ingredients become generally recognized as safe and effective antacids, the monograph will be amended to include charcoal and/or kaolin and shall specify the applicable specific drug interaction warnings. Marketing of antacids containing charcoal or kaolin as active ingredients may continue until June 4, 1976, provided the manufacturer or distributor of such products undertakes adequate testing to prove effectiveness; the product, if it claims to be antacid, meets the in vitro antacid effectiveness standard in the antacid monograph and the label contains the specified drug interaction precaution.

Therefore, pursuant to provisions of the Federal Food, Drug and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 321, 352, 355, 371); the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended; 5 U.S.C. 553, 554, 702, 703, 704) and under authority delegated to the Commissioner (21 CFR 2.210), 21 CFR Part 330 is amended in § 330.1 by revising paragraph (g) and by revoking and reserving paragraph (i) as follows:

§ 330.1 General conditions for general recognition as safe, effective, and not misbranded.

* * * * *

(g) The labeling for all drugs contains the general warning: "Keep this and all drugs out of the reach of children." The labeling of drugs used for oral administration shall also state: "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling for drugs administered rectally or used topically shall state: "In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately." The Food and Drug Administration will grant an exemption from these general warnings where appropriate upon petition, which shall be maintained in a permanent file for public review by the Office of the Hearing Clerk, Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, MD 20852.

* * * * *

(i) [Reserved]

* * * * *

(The Federal Food, Drug, and Cosmetic Act secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948; (21 U.S.C. 321, 352, 355, 371); the Administrative Procedure Act secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704))

Effective date. This order shall be effective March 13, 1975.

Dated: March 5, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-6559 Filed 3-12-75;8:45 am]

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

Amendments to Monographs for OTC Antacid and Antiflatulent Products

In the FEDERAL REGISTER of June 4, 1974 (39 FR 19862) the Commissioner of Food and Drugs promulgated a final order for Antacid and Antiflatulent OTC drug products generally recognized as safe and effective and not misbranded. Section 331.30(a) for the labeling indications for antacid products included "The labeling of the product represents or suggests the product as an "antacid" to alleviate the following symptoms: "Heartburn," "sour stomach," and/or "acid indigestion." Section 332.30(a) for the labeling indications for antiflatulent products included "The labeling of the product represents or suggests the product as an "antiflatulent" and/or "to alleviate or relieve the symptoms of gas."

The Commissioner believes that the consumer should have available the most reliable, helpful drug information. The purpose of OTC medication is to permit consumers to engage in self-medication without medical or other professional supervision. It has been brought to the Commissioner's attention that the terms "represents or suggests" in the labeling requirements for OTC antacid (331.30 (a)) and antiflatulent (332.30(a)) drug products raises the question whether analogous or similar terms may be used.

The Commissioner advises that paragraph 49 of the preamble to the tentative final order published in the FEDERAL REGISTER of November 12, 1973 (38 FR 31260) explicitly dealt with this matter. Some of the comments on the proposed monograph published in the FEDERAL REGISTER of April 5, 1973 (38 FR 8714) had contended that the four allowed terms, "heartburn," "sour stomach," "acid indigestion," and "antacid" lack meaning to the consumer and were too restrictive. The Commissioner concluded, however, that the terms recommended by the Panel fully meet the intent of the regulation, that allowing each manufacturer to select the words to be used would result in continued consumer confusion and deception, and therefore that the evidence presented does not justify expansion of the present number of permitted terms. Accordingly, no change was made in the tentative final order or in the final regulation published in the FEDERAL REGISTER of June 4, 1974 (39 FR 19862).

In order to make this point clearer, the Commissioner has concluded that §§ 331.30(a) and 332.30(a) should be amended to state that the labeling of the product shall "identify" the product with only the specified terms. This fully reflects the intent and purpose of the regulation, as previously published.

The Commissioner notes that the regulation was not intended to prevent the use of descriptive phrases or adjectives, e.g., "sparkling" antacid. In all instances, however, the products must be identified using the specified terms permitted by the regulation.

Because this notice in no way changes the regulation, but only confirms and clarifies its meaning as previously set forth, the Commissioner concludes that notice, public procedure, and delayed effective date are unnecessary and contrary to the public interest.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 321, 352, 355, 371, the Administrative Procedure Act (secs. 4,

5, 10, 60 Stat. 238 and 243 as amended; 5 U.S.C. 553, 554, 702, 703, 704) and under authority delegated to the Commissioner (21 CFR 2.120), 21 CFR Parts 331 and 332 are amended as follows:

1. In Part 331 by revising § 331.30(a) to read as follows:

§ 331.30 Labeling of antacid products.

(a) *Indications.* The labeling of the product shall identify the product as an "antacid" to alleviate the following symptoms: "heartburn," "sour stomach," and/or "acid indigestion."

* * * * *

2. In Part 332 by revising § 332.30(a) to read as follows:

§ 332.30 Labeling of antiflatulent products.

(a) *Indications.* The labeling of the product shall identify the product as an "antiflatulent" and/or "to alleviate or relieve the symptoms of gas."

* * * * *

(The Federal Food, Drug, and Cosmetic Act secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948; 21 U.S.C. 321, 352, 355, 371; the Administrative Procedure Act secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704))

Effective date. This order shall become effective April 14, 1975.

Dated: March 5, 1975.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.75-6560 Filed 3-12-75;8:45 am]

SUBCHAPTER F—BIOLOGICS

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINE

Measles Virus Vaccine, Live, Attenuated and Rubella Virus Vaccine, Live; Deletion of Canine Renal Tissue Cultures

The Food and Drug Administration is conducting a review of the existing regulations governing biological products to assure that the criteria of safety, purity, and potency established by such regulations are updated to remain consistent with the judgment of the scientific community. Incidental to the subject review, the Commissioner of Food and Drugs finds that the regulations governing Measles Virus Vaccine, Live, Attenuated (21 CFR 630.30 through 630.37) and Rubella Virus Vaccine, Live (21 CFR 630.60 through 630.67) should be amended to delete reference to canine renal tissue cultures. This order is effective March 13, 1975.

The procedures for the propagation of measles and rubella vaccines in canine renal tissue cultures were added to the additional standards for these products in response to license applications submitted in 1963 and 1969. These revisions to the standards for Measles Virus Vaccine, Live, Attenuated and Rubella Virus Vaccine, Live were published in the FEDERAL REGISTER of October 22, 1963 (28 FR 11268) and June 7, 1969 (34 FR 9072), respectively, codified in 42 CFR Part 73, transferred to 21 CFR Part 273 by publication in the FEDERAL REGISTER of August 9, 1972 (37 FR 15993), and subsequently recodified as 21 CFR Part 630 by publication in the FEDERAL REGISTER of November 20, 1973 (38 FR 32048).

In 1973 the subject licenses for the manufacture of these vaccines from viruses propagated in canine renal cell cultures were revoked in response to notices from the manufacturer, given pursuant to 21 CFR 601.4, indicating its intention to discontinue manufacture of the products. Since the subject vaccines prepared from viruses propagated in canine renal cell cultures are no longer being manufactured, nor are there indications that they will be manufactured in the foreseeable future, there is no need for maintaining requirements concerning canine renal cell cultures in the aforementioned regulations. Accordingly, the Commissioner concludes that the standards governing the manufacture of Measles Virus Vaccine, Live, Attenuated and Rubella Virus Vaccine, Live, should be amended by deleting reference to canine renal cell cultures.

Therefore, pursuant to provisions of the Public Health Service Act (sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262), and under authority delegated to the Commissioner (21 CFR 2.120), Part 630 is amended as follows:

1. In § 630.30 by revising paragraphs (b) and (c)(4) to read as follows:

§ 630.30 Measles virus vaccine, live, attenuated.

* * * * *

(b) *Criteria for acceptable strains of attenuated measles virus.* Strains of attenuated measles virus used in the manufacture of vaccine shall be identified by (1) historical records, including origin and manipulation during attenuation and (2) antigenic specificity as measles virus as demonstrated by tissue culture neutralization tests. Strains used for the manufacture of Measles Virus Vaccine, Live, Attenuated, shall have been shown to be safe and potent in man by field studies with experimental vaccines. The vaccine shall have been demonstrated as safe and potent in at least 10,000 susceptible persons. Susceptibility shall be shown by the absence of neutralizing or other antibodies against measles virus, or by other appropriate methods. Seed virus used for vaccine manufacture shall be free of all demonstrable extraneous viable microbial agents except for unavoidable bacteriophage.

(c) * * *

(4) *Need for additional neurovirulence safety testing.* A neurovirulence safety test as prescribed in this paragraph shall be performed on vaccine from five consecutive lots whenever a new production seed lot is introduced or whenever the source of cell culture substrate must be reestablished and recertified as prescribed in § 630.32 (a) and (b) of this Part.

2. In § 630.32 by revising paragraph (a) and deleting and reserving paragraph (c) as follows:

§ 630.32 Manufacture of live, attenuated, measles virus vaccine.

(a) *Virus cultures.* Virus shall be propagated in chick embryo tissue cultures.

* * * * *

(c) [Reserved]

* * * * *

§ 630.35 [Amended]

3. In § 630.35 *Test for safety* by deleting and reserving paragraph (b).

4. In § 630.60 by revising paragraph (e)(3) to read as follows:

§ 630.60 Rubella virus vaccine, live.

* * * * *

(e) * * *

(3) *Need for additional neurovirulence safety testing.* A neurovirulence safety test as prescribed in this paragraph shall be performed on vaccine from five consecutive lots whenever a new production seed lot is introduced or whenever the source of cell culture substrate must be reestablished and recertified as prescribed in § 630.62 (a), (b) and (d) of this Part.

5. In § 630.62 by revising paragraph (a) and deleting and reserving paragraph (c), as follows:

§ 630.62 Production.

(a) *Virus cultures.* Rubella virus shall be propagated in duck embryo cell cultures or rabbit renal cell cultures.

* * * * *

(c) [Reserved]

* * * * *

§ 630.65 [Amended]

6. In § 630.65 *Test for safety* by deleting and reserving paragraph (b).

Pursuant to the Administrative Procedure Act (5 U.S.C. 553(b) and (d)), the Commissioner concludes that notice, public procedure and delayed effective date are unnecessary for the promulgation of this order inasmuch as it does not impose a duty or burden on any person, but rather updates the regulations to delete requirements for licenses no longer in effect.

Effective date. This order shall be effective March 13, 1975.

(Sec. 351, 58 Stat. 702, as amended; 42 U.S.C. 262.)

Dated: March 7, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75-6564 Filed 3-12-75;8:45 am]

Title 27—Alcohol, Tobacco Products and Firearms

CHAPTER I—BUREAU OF ALCOHOL, TOBACCO AND FIREARMS, DEPARTMENT OF THE TREASURY

[T.D. ATF-15]

PART 6—INDUCEMENTS FURNISHED TO RETAILERS

Signs and Advertising Specialties Furnished to Retailers; Amended Limitations

The purpose of these amendments to 27 CFR Part 6, Inducements Furnished